EXHIBIT 26

Whitelaw Compliance Group, LLC.

Examination of Compliance Standards for Opioid Manufacturers and Distributors

Prepared For	Prepared By
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION *IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION* Case No. 18-OP-45132 (N.D. Ohio) MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster	Dr. Seth B. Whitelaw President & CEO Whitelaw Compliance Group, LLC. April 15, 2019

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PART III: Defining What Good Looks Like

6 Applying the Standards

As discussed in Part II, by the mid-1990s, the concept of "what good looks like" was established both in the context of corporate and controlled substances (a.k.a. anti-diversion) compliance. From that point forward it was clear that companies in the pharmaceutical industry, including manufacturers and distributors of opioid products, could develop effective internal controls to achieve the objectives to prevent and detect criminal conduct by an organization's employees and agents working on behalf of the organization and to guard against theft and diversion of controlled substances.[94]

In the U.S., the basic regulatory construct for pharmaceuticals, regardless of the agency, is to provide the industry with "what" is expected, but not dictate "how" those expectations are achieved. The "how" is left to the individual organizations to determine the best methods to comply. This approach is true in the case of the OIG, DEA, and even the FDA.[95]

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[94] *See* Appendix B, Figures 2 and 3 for diagrams outlining a controlled substances compliance program (a.k.a. anti-diversion program) and a corporate compliance program.

[95] *See, e.g.*, U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991) ["FSGs 1991"]; J. Rannazzisi letters to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007 and Jun. 12, 2012) (These letters were not McKesson specific but sent to all DEA registrants), MCKMDL00478906, MCKMDL00615308, MCKMDL00478910, MCKMDL00449807 ["DEA (date) Letter"]; U.S. Food and Drug Admin., Center for Drug Evaluation and Research, *Facts About the Current Good Manufacturing Practices (CGMPs)*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105 htm, (page last updated Jun. 25, 2018) (last accessed Dec. 8, 2018) ("The CGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures.").